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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/230,137	08/10/1999	ROBERT WILLIAM CUNNINGHAM	23861-001	4790

7590 09/09/2003

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EXAMINER

CROSS, LATOYA I

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 09/09/2003

22

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/230,137

Applicant(s)

CUNNINGHAM

Examiner

LaToya I. Cross

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 and 27-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 and 27-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

This Office Action is in response to Applicants' amendment filed on June 16, 2003 and entered as Paper No. 21. Claims 1-25 and 27-31 are pending.

Claim Objections

1. Claims 29-31 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must be written in the alternative. See MPEP § 608.01(n).

Applicants' amendment filed on August 24, 2001 (Paper No. 9) contains amended claims 29 and 31 written in improper multiple dependent form. No amendment to those claims has been filed. In response to this Office Action, Applicants should provide an amendment to correct the improper multiple dependent claims.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1-25 and 27-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Charlton et al in view of Jenkins et al.

Charlton et al teach a device containing a substrate (12) having several layers (14, 16, 18

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and 20) mounted thereto. The substrate contains an aperture (24), which is a throughbore. The layer (14) is mounted directly to substrate (12) and is equivalent to Applicants' claimed supportive layer. Layer (14) has guide means for directly fluid sample through the device. The guide means comprises a chamber (26) where fluid sample is deposited. Connected to chamber (26) is a capillary channel (28) which leads to an overflow containment chamber (32). Excess fluid flows through channel (28) and into chamber (32). Channel (28) and chamber (32) are used to determine whether a sufficient amount of sample has been taken in. At col. 3, lines 41-50, Charlton et al explain that once the user sees fluid in the channel (28) or in the chamber (32), the device is filled with fluid. Conversely, if no sample is seen in channel (28) or chamber (32), then additional sample is needed. With respect to claim 3, layer (14) is sandwiched between multiple layers (see figure 2). The device has a handle end for handling, as in claim 6. With respect to claims 7 and 8, Charlton et al teach that the layers are constructed of plastic materials, which are hydrophobic. At col. 4, line 63 – col. 5, line 5, Charlton et al teach that the diameter of the chamber (26) is 0.5 cm and the aperture has a diameter of 5.1 cm, as in claims 12 and 13.

Charlton et al differ from the instantly claimed invention in that in Charlton et al, the visual inspection for the presence of the fluid sample is used to determine whether fluid is present in channel (28) or chamber (32), whereas, Applicants claim the use of an indicator to determine the presence of enough fluid. With respect to claims 9 and 10, Charlton et al do not teach an aperture over the indicator portion. With respect to claims 19-25, Charlton et al do not teach an identification means.

Jenkins et al teach a device for collecting a fluid sample. The device has an aperture in a support member, with an absorbent member attached to the support. Fluid sample is applied

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through the aperture (32) and is deposited on the absorbent material (52). Downstream from where the sample is deposited, there exists an indicator reagent (56), which provides a color change when enough sample has been taken up by the absorbent material (col. 6, lines 59-65). The user will observe the color change to determine when enough sample is present, as recited in claims 1, 17 and 31. With respect to claims 9 and 10, Jenkins et al teach an aperture (36) located over the indicator to allow the user to view any color change. With respect to claim 11, figure 10 of Jenkins et al shows the indicator (56) absorbed onto the absorbent material. Regarding claims 14-16, Jenkins et al teach using cotton for the absorbent material (col. 3, lines 37-38). With respect to claims 18, 29 and 30, Jenkins et al teach using a bar code on the device for identification (col. 4, lines 39-45). With respect to claims 19-25, Jenkins et al teach a pouch (80) to contain the device.

It would have been obvious to one of ordinary skill in the art to use a colorimetric reagent indicator in the device of Charlton et al because the colorimetric reagent would provide a clear color change for the user to observe in determining whether sufficient sample has been up taken. A colorimetric indicator would be especially advantageous where the sample is transparent or colorless and its presence by mere observation could not clearly be seen. Further, it would have been obvious to one of ordinary skill in the art to include an aperture over the indicator area of Charlton et al to allow the user to have a particular area to focus in on when observing whether there is sufficient sample. It would have also been obvious to incorporate a bar code onto the device of Charlton et al so that the sample can be identified later.

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Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be obvious, within the meaning of 35 USC 103, in view of the teachings of Charlton et al and Jenkins et al.

Response to Arguments

5. Applicant's arguments filed June 16, 2003 have been fully considered but they are not persuasive. With respect to the rejection over Charlton et al in view of Jenkins et al, Applicants argue that the Charlton et al reference does not teach a throughbore that is intended to allow a portion of the sample deposition area to be punched out. In response, Charlton et al does teach a throughbore, denoted as reference character 24, which provides a hole that runs through all of the layers and causes the sample to be deposited at a chamber 34. While Charlton et al may not teach that the throughbore is used to allowing a portion of the sample deposition area to be punched out, Applicants should note that in claims directed to an apparatus, the function of the structures is not sufficient to patentably distinguish the invention over the prior art. Applicants' claims must be structurally different so as to be patentable over the prior art. See MPEP 2114. Contrary to Applicants' assertion, the rejection does not refer to Jenkins et al for the presence of a throughbore. Jenkins et al is used to show the conventional use of a bar code, an indicator of sufficient sample uptake and absorbent materials. Applicant's amendment does not structurally distinguish the invention from that of the prior art. Thus, the rejection is maintained.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 703-305-7360. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 703-308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

LIC

September 7, 2003


Jill Warden
Supervisory Patent Examiner
Technology Center 1700